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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,395	02/25/2002	Frank Diehl	22012.PUS	4534
7590 11/12/2003				
Eugene E. Renz, Jr., P.C. 205 North Monroe Street Post Office Box 2056 Media, PA 19063-9056				
			EXAMINER FORMAN, BETTY J	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,395	DIEHL ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23 is/are allowed.
- 6) ☒ Claim(s) 13-20 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 August 2003 in which claims 1-12 were canceled and claims 13-26 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 March 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the new grounds for rejection. New grounds for rejection necessitated by the amendments are discussed.

Claims 13-26 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-15, 17 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cronin et al (U.S. Patent No. 6,045,996, issued 4 April 2000).

Regarding Claim 13, Cronin et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in a solvent containing at least one betaine and applying the nucleic acid-betaine solution to the carrier whereby the nucleic acids are bound to the carrier via hybridization to probe immobilized on the carrier (Column 10, line 48-Column 11, line 20).

Regarding Claim 14, Cronin et al disclose the process wherein the betaine is trimethylammonium acetate (Column 4, lines 22-31).

Regarding Claim 15, Cronin et al disclose the process wherein the betaine is present at a concentration of 8mM to 6.5M (Column 4, lines 3-31 and Column 5, lines 11-12).

Regarding Claim 17, Cronin et al disclose the process wherein the carrier is made of glass (Column 10, lines 17-19).

Regarding Claim 24, Cronin et al disclose a process for binding nucleic acids to a carrier comprising adding a betaine to a solution of nucleic acids and subsequently applying the solution to a carrier to bind the nucleic acids to the carrier via hybridization (Column 10, line 48-Column 11, line 20).

Regarding Claim 25, Cronin et al disclose a process comprising the steps of dissolving nucleic acids and a betaine in a solvent to obtain a solution, applying the solution to onto microarray to bind the nucleic acids to the surface of the microarrays via hybridization (Column 10, line 48-Column 11, line 20).

Regarding Claim 26, Cronin et al disclose a process for binding nucleic acids to a carrier comprising dissolving nucleic acids and a betaine in a solvent to obtain a solution of nucleic acids and betaines and applying the solution to a carrier to bind the nucleic acids to the carrier via hybridization (Column 10, line 48-Column 11, line 20).

R sponse to Arguments

4. Applicant has added the new limitation "spotting solution" and argues that Cronin et al does not teach the claimed spotting solution. The argument has been considered but is not

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found persuasive because the instantly claimed spotting solution is defined simply as a solution containing nucleic acids and a betaine. The claims are not limited to a method step of "spotting" and the claims do not limit the spotting solution to spotting. Therefore, Applicant's assertion that the instant claimed spotting solution is different from the solution of Cronin et al is not found persuasive.

Applicant further argues that the nucleic acids of Cronin et al are hybridized to probes immobilized on an array and differ from the instantly claimed nucleic acids which are immobilized on the array. The argument has been considered but is not found persuasive because the instant claims are broadly drawn to binding nucleic acids to a carrier (or microarray).

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

The claims are given the broadest reasonable interpretation consistent with the broad claim language wherein the nucleic acids are bound to the carrier. The instantly claimed binding is interpreted to encompass any means of binding the nucleic acid to the carrier e.g. hydrophobic interaction, hydrogen binding (e.g. hybridization), covalent binding and etc. Applicant appears to be limiting the claimed binding to a direct contact between the nucleic acid and the carrier. However, the claims are not so limited. Because the claims are broadly drawn to binding the nucleic acid to the carrier, the teaching of Cronin et al is encompassed by the claimed invention.

Applicant argues that the instant claims are drawn to methods of spotting and binding whereby probes are immobilized onto the carrier and microarrays are produced which is very different from the hybridization method of Cronin et al. The argument has been considered

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but is not found persuasive because Claims do not recite method steps requiring “spotting” or “immobilization” or production of a microarray. While Claim 25 is drawn to a method for manufacturing microarrays, method step (b) merely requires “applying said spotting solution of nucleic acids onto said microarrays”. As such, the method steps of Claim 25 do not produce a microarray, but in contrast merely “apply.... nucleic acids to the surface of a microarray”. Therefore, the limitations of Claim 25 apply nucleic acids to a microarray which already exists. Furthermore, the claims do not recite method steps of spotting, but merely applying which encompasses various means of putting the nucleic acids onto the carrier. And the method steps do not recite limitations of immobilizing, but merely binding which as discussed above encompasses various means of relating the nucleic acids to the carrier. Therefore, the arguments regarding spotting, immobilization, and microarray production are not commensurate in scope with the instant claims.

5. Claims 13-15, 17, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Koster (U.S. Patent No. 5,547,835, issued 20 August 1996).

Regarding Claim 13, Koster discloses a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67).

Regarding Claim 14, Koster discloses the process wherein the betaine is trimethylammonium acetate (TEAA) (Column 21, lines 39-67).

Regarding Claim 15, Koster discloses the process wherein the betaine is present in a spotting solution at a concentration range of 8mM to 6.5M (Column 21, lines 39-67).

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Regarding Claim 17, Koster discloses the process wherein the carrier is made of glass (Column 14, lines 5-10).

Regarding Claim 24, Koster discloses a process for binding nucleic acids to a carrier comprising adding betaine to a solution of nucleic acids to produce a solution containing nucleic acids and betaine and applying the solution to a carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67).

Regarding Claim 26, Koster discloses a process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution to produce a solution containing nucleic acids and betaine and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (U.S. Patent No. 5,547,835, issued 20 August 1996) in view of DeRisi et al (Science, 24 October 1997, 278: 680-686).

Regarding Claim 16, Koster teaches the process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to

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bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67) wherein the betaine/nucleic acid solution in a buffered solution at about pH 7 (Column 21, lines 58-67) but they do not teach the buffer is sodium chloride and sodium citrate (SSC). However, SSC was routinely practiced in the art as a buffer for spotting solutions as taught by DeRisi et al (page 685, ¶ 9). While DeRisi et al do not teach the specific concentrations of SSC, it would have been obvious to one of ordinary skill in the art to use routine experimentation to derive optimal concentrations to thereby maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the SSC buffer of DeRisi et al to the buffered solution of Koster to thereby effectively spot the nucleic acids onto the carrier as taught by DeRisi (page 685, ¶ 9).

Regarding Claims 18-20, Koster teaches the process for binding nucleic acids to a carrier comprising dissolving nucleic acids in betaine solution and apply the solution to the carrier to bind the nucleic acids to the carrier (Example 1, Column 21, lines 14-67) wherein the carrier is made of glass (Column 14, lines 5-10) but they do not teach coating the glass carrier. However, it was well known in the art at the time the claimed invention was made that glass carriers for nucleic acids were coated with poly-L-lysine as taught by DeRisi et al (page 685, ¶ 9). DeRisi et al further teach that the glass carrier is further treated with a solution of succinic anhydride and an acylating catalyst in a nonpolyar non-aqueous solvent to thereby block non-specific binding (page 685, ¶ 9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the poly-L-lysine coating followed by treatment with succinic anhydride and an acylating catalyst as taught by DeRisi et al to the

glass carrier of Koster for the expected benefit of effectively immobilizing nucleic acids and blocking non-specific binding as taught by DeRisi et al (page 685, ¶ 9).

NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

8. This application contains sequence disclosures (page 12) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN A PERIOD OF TIME WHICH IS COEXTENSIVE WITH THE TIME TO REPLY TO THE ABOVE OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. Claims 21—23 are free of the prior art and may be placed in condition for allowance following resolution of the above rejections.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
November 6, 2003